g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

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h. placing an acid alcohol sample consisting of approximately 25 μl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 μl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. using the strand pattern to detect a change in the body of the human donor.

REMARKS

Applicant respectfully requests reconsideration of the present Application in view of the foregoing amendments and in view of the arguments which follow.

A. ENABLEMENT

The examiner has rejected all pending claims (1-10) pursuant to 35 U.S.C. §112, (first paragraph) asserting that the patent application's "specification does not reasonably provide enablement for identifying any change in the body of a human being caused by any physiological or pathological condition." More specifically, although the examiner acknowledges that the specification does teach the detection of DNA complex patterns in pregnant women and women with breast and cervical cancer, he argues that the "specification provides no guidance regarding methods for identification of any other change in the body of a human being caused by other physiological or pathological condition and no guidance has been provided to detect DNA [complex] patterns in male patients." The examiner concludes that it is "highly unpredictable whether or what other

diseases would be detected by identifying DNA [complex patterns] extracted from blood," and arrives at this conclusion based upon six (6) facts. Applicants discuss below each fact in turn:

(1) Reproducible DNA Patterns.

The examiner states that DNA patterns, even from the same pregnant woman, are not reproducible as shown in Figures 2A – 3E of the specification. Applicants respectfully submit that the examiner has misconstrued the invention disclosed in the specification. With regard to Figures 2A – 2E, those figures comprise the DNA complex patterns of **different** pregnant woman at varying stages of pregnancy, from six (6) weeks to ten (10) weeks, and Figure 2F sets forth the pattern formed from a pregnant woman carrying twins. Further, applicants do not disclose nor claim the ability to form patterns of DNA which has been separated from its nucleoprotein complex. Rather, applicants' invention includes the recognition that the patterns formed from **DNA and its associated nucleoprotein complex** ("DNA complex") can be used to determine the sex of a fetus within just a few weeks after the inception of pregnancy. As described in the specification (page 10, line 9 – page 11, line 4), the patterns of DNA complex from women carrying a female fetus are readily distinguishable from the patterns formed from women carrying a male fetus. The patterns formed from women carrying a female fetus exhibit "a single and approximately circular or polygonal ring shape" (page 10, lines 17-18). In contrast, the patterns formed from women carrying a male fetus exhibit a "generally linear pattern, or a linear pattern in combination with one or more elongated or collapsed ring patterns" (page 11, lines 1-2). Accordingly, the invention's ability to detect the sex of a fetus is based upon the comparison of the patterns formed by the DNA

complex of a woman carrying a female fetus to the patterns formed by the DNA complex of a women carrying a male fetus. Circular or polygonal shaped patterns indicate a female fetus, and linear or elongated ring patterns indicate a male.

Applicants' experiments with pregnant women and nonpregnant women also revealed that the DNA complex patterns for any given blood sample from the same person will exhibit practically identical shapes. Thus, the method of the present invention, for any given blood sample, is highly reproducible. But, it is equally important that applicants have experimentally established that the DNA complex patterns from women carrying a female fetus are easily distinguished from the male fetus patterns.

(2) Correlation between Physiological or Pathological Conditions and DNA Complex Patterns.

Next, the examiner asserts that there is no correlation between the physiological or pathological conditions and the DNA complex pattern. Again, the examiner has misconstrued the invention. With regard to a pregnant woman, the correlation is the comparison of the DNA complex pattern to the two predominate patterns that have been established by using the present invention to process the blood of approximately 1,000 pregnant women (Declaration of G. Wu, ¶ 4). If the pattern is circular or polygonal in shape, the fetus is a female; if the pattern is linear or elongated in shape, the fetus is a male.

With regard to pathological conditions, the correlation is the comparison of the DNA complex pattern to the pattern of a healthy person. As disclosed in the specification, Figure 4 is a representation of a typical pattern formed from the blood of a healthy person, and is based upon using the present invention to process the blood of

approximately 300 healthy women and 300 healthy men (Declaration of G. Wu, ¶ 3). The experiments revealed that healthy persons exhibit DNA complex patterns that consist of linear strands that are smooth or are circular in shape and smooth. On the other hand, the DNA complex patterns of women with breast or cervical cancer consist of strands that contain beaded segments and branches (Figure 5; breast cancer) or contain a loop and branches (Figure 6; cervical cancer).

(3) SEM Valve.

The examiner further criticizes the specification for failure to disclose a Scanning Electron Microscope valve in order to quantify the DNA pattern. As noted above, however, the present invention does not disclose a method of isolating a DNA molecule. Rather, the patterns that are formed by utilizing the inventive method comprise an aggregation of countless DNA molecules and an associated nucleoprotein complex. Further, the patterns are visible under magnification of an ordinary optical microscope. The application does not attempt to disclose and claim a quantitative or numerical method of detecting changes in DNA molecules. Instead, the invention comprises a qualitative analysis which provides a method of detecting the sex of a fetus and a change in the body of a human being who has been exposed to a pathological condition. The change in the body is not detected by quantitatively measuring changes in a nearly invisible DNA molecule, but, in the case of a disease, the change is detected by comparing the pattern of aggregated DNA complex of a healthy person to the pattern of someone who has a significant disease. And, in the case of pregnancy, the inventive method is able to determine the sex of the fetus by comparing the DNA complex pattern to the patterns formed from the blood of women carrying male and female fetuses.

(4) Experimental Control.

The examiner cites the lack of control (*i.e.,* a normal DNA pattern) for an additional reason why the results of the invention are unpredictable. To the contrary, the specification does disclose operable controls. In the instance of cancer, the control is shown in Figure 4, which is illustrative of the DNA complex pattern formed from a healthy person. Further, in the case of the sex of a fetus, the controls are the two (2) distinct patterns formed from the blood of a woman carrying either a male or female fetus.

(5) Phenol Extraction.

The examiner also challenges the disclosure on the basis that the phenol extraction strips off all proteins from the cellular tissue and causes the loss of some nucleic acids. To the contrary, phenol by itself cannot strip off all of the nucleoprotein complex. In order for the phenol to do so, the tissue must initially be treated with protease (*e.g.,* a histone or histo protein). The present invention does not include this step. (J. SHAMBROOK ET AL., MOLECULAR CLONING, A LABORATORY MANUAL Book 2, Chapter 9 (Cold Spring Laboratory Press, 2d ed. 1989).)

(6) Changes of DNA Structure within White Blood Cell.

The examiner states that the DNA structure would be expected to change depending on the phase and development of white blood cells and implies that the present invention does not disclose a method of quantifying the change. But the present invention is not directed to identifying the transient changes to the DNA structure related to cell growth. Rather, the present invention relies, in part, upon the fact that the DNA structure changes as part of a rearrangement process which takes place in bone marrow and which has been shown to be critical to the production of a vast variety of white blood cells with

each variety containing a uniquely rearranged DNA structure. What is significant to the present invention is that after the mature white blood cells enter the blood stream, some of the cells produce specific clones as part of an immunological response to the exposure to an antigen, such as a physiological or pathological condition. If the physiological or pathological condition is significant (*e.g.,* pregnancy or cancer), the immunological response produces large numbers of specific clones which are designed to protect the body from the antigen. Applicants believe that the change in the DNA complex pattern of a healthy person after the person has been exposed to a physiological or pathological condition is most probably due to this substantial increase in the volume of white blood cell clones, as compared to the volume of all other white blood cells in the blood. (G. Wu Declaration, ¶ 8).

Finally, the examiner concludes that based upon the unpredictable nature of traditional DNA isolation and analysis, the method of the present invention "will not predictably detect or function to detect any particular disease." Contrary to the examiner's conclusion, applicants do not claim the ability to predict the existence of a specific disease based upon a correlation to a specific DNA complex pattern produced by using the method disclosed in the specification. Rather, applicants claim that they have identified the essential characteristic of the DNA complex patterns of healthy persons in which their patterns have predominately smooth linear strands or circularly shaped smooth strands. Applicants further claim that their method of processing human blood allows someone skilled in the art to readily recognize changes in the predominately smooth strands by using an optical microscope to detect the presence or absence of beads within a smooth strand, a loop within a strand and/or significant branching coming off of a

smooth strand. Applicants' experiments have correlated a beaded strand with some branching to the presence of breast cancer (see Figure 5) and have correlated a looped strand with some branching with cervical cancer (see Figure 6). These results are significant not because a specific DNA complex pattern can, at the present time, be associated to a specific disease, but due to the fact that the method can be used as a diagnostic screen to indicate whether a person is being subjected to a significant pathological condition, warranting further medical evaluation and diagnostic techniques. In other words, the relatively simple blood test described in the specification can be used to tell a person whether or not he or she is healthy. If the test indicates the presence of disease, earlier detection would then be possible using more expensive and invasive techniques like an MRI, a CAT scan and a colonscopy. Naturally, a normal test result would provide a general sense of well being to the patient, possibly removing a generalized fear that he or she has cancer or some other serious disease.

Concerning the sex of a fetus, however, applicants claim that the sex of a fetus can be readily determined by using the method of the present invention to process the blood of a pregnant woman. As described in detail above, applicants have identified two (2) predominate strand patterns from the blood of a pregnant woman which determine the sex of a fetus within a few weeks of conception.

B. CLAIMS

The examiner has rejected claims 1 through 5 as being vague and indefinite because of applicants' use of the phrases "one volume," "two volumes," "four volumes," and "twenty-five volumes." Applicants assume that the examiner's objection is actually based upon the fact that in each claim the initial volume measurement described is "two

volumes of Tris-buffer," rather than "one volume of Tris-buffer." Accordingly, applicants have submitted amended claims which disclose "one (1) volume of Tris-buffer," rather than "two (2) volumes of Tris-buffer," and similarly reduce all other volumes by a half. In any event, as described in the specification, it is the relative proportions of the various chemicals that is important to the invention, not the actual quantities used.

Claims 1 through 10 have been rejected due to the recitation of the phrases "allow" and "can be used" which the examiner asserts renders the claims indefinite because it is unclear whether the limitations following each phrase are part of the claimed invention. Applicants have submitted amended claims in response to these rejections.

Respectfully submitted,

Date 5/17/02 By _____

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Application No.: 09/764,783
Filed: January 17, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

1. **(Amended)** A method of ~~processing human blood samples~~determining the sex of a fetus comprising:

a. mixing a sample of ~~human~~ blood from a pregnant woman with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately ~~two~~one ~~(~~1~~2)~~ volume~~s~~ of Tris-buffer;

ii. adding approximately ~~one~~a half ~~(~~1½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) ~~two (2)~~ volume~~s~~ of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately ~~four~~ two (~~4~~2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately ~~one (1)~~a half (½) volume of chloroform and approximately a half (½) ~~one (1)~~ volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris long enough to allow the structural components of the DNA complex of the blood cells to aggregate;

h. placing an acid alcohol sample consisting of approximately ~~twenty-five (25)~~twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately one fifth (1/5~~4~~) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a pattern on the slide; and ~~which can be used to identify a change in the body of a human being caused by a physiological or pathological condition.~~

j. determining that the sex of the fetus is female if the shape of the strand pattern is approximately circular or polygonal, or that the sex of the fetus is male if the shape of the strand pattern is generally linear or generally linear in combination with at least one elongated ring.

2. **(Amended)** ~~The method of claim 1 in which the Tris-buffer consists of 0.5 M Tris, 0.2 M EDTA, 0.6% NaCl, having a pH of between 10.3 and 10.4.~~

A method of determining the sex of a fetus comprising:

a. mixing a sample of blood from a pregnant woman with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately 5 µl of Tris-buffer;

ii. adding approximately 2.5 µl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 µl of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately 10 µl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 µl of chloroform and approximately 2.5 µl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 µl of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately 1.0 µl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. determining that the sex of the fetus is female if the shape of the strand pattern is approximately circular or polygonal, or that the sex of the fetus is male if the shape of the strand pattern is generally linear or generally linear in combination with at least one elongated ring.

3. **(Amended)** The method of claim 1 or 2 in which the ~~step of centrifuging the first blood cell mixture is performed for approximately ten (10) minutes at approximately 11,000 rpm~~ Tris-buffer consists of 0.5 M Tris, 0.2 M EDTA, 0.6% NaCl, having a pH of between 10.3 and 10.4..

4. **(Amended)** The method of claim 1 or 2 in which the step of centrifuging the ~~second~~ first~~-~~ blood cell mixture is performed for approximately ~~fifteen~~ ten (~~15~~10) minutes at ~~approximately~~ 11,000 rpm.

5. **(Amended)** The method of claim 1 or 2 in which the step of ~~cooling the~~ centrifuging the ~~second~~ first~~-~~ blood cell mixture is performed ~~by placing the second liquid phase on ice~~ for approximately fifteen (15) minutes at 11,000 rpm.

6. **(Amended)** A method of claim 1 or 2 in which the step of coolinf the second liquid blood cell mixture is performed for approximately fifteen (15) minutes at 11,000 rpm. ~~processing human blood samples comprising:~~

~~a.mixing a sample of human blood with an anticoagulant to form an anti-coagulated blood mixture;~~

~~b.centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;~~

~~c.preparing a first blood cell mixture in accordance with the following steps:~~

~~i.preparing approximately 5 µl of Tris-buffer;~~

~~ii.adding approximately 2.5 µl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 µl of Tris-buffer to produce a buffer diluted phenol; and~~

~~iii.adding approximately 10 µl of the blood cells to the buffer diluted phenol;~~

~~e.centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;~~

~~f. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 µl of chloroform and approximately 2.5 µl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;~~

~~g. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;~~

~~h. cooling the second liquid phase and second blood cell debris long enough to allow the structural components of the DNA complex of the blood cells to aggregate;~~

~~i. placing an acid alcohol sample consisting of approximately 25 µl of freshly made 20% acid alcohol on a slide; and~~

~~j. adding a blood cell sample consisting of approximately 1 µl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a pattern on the slide which can be used to identify a change in the body of a human being caused by a physiological or pathological condition.~~

7. **(Amended)** ~~The method of claim 6 in which the Tris-buffer consists of 0.5 M Tris, 0.2 M EDTA, 0.6% NaCl, having a pH of between 10.3 and 10.4.~~

A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of blood from a human donor with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately one (1) volume of Tris-buffer;

ii. adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. using the strand pattern to detect a change in the body of the human donor.

8. **(Amended)** ~~The method of claim 6 in which the step of centrifuging the first blood cell mixture is performed for approximately ten (10) minutes at approximately 11,000 rpm.~~

A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of the human blood with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately 5 µl of Tris-buffer;

ii. adding approximately 2.5 µl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 µl of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately 10 µl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 µl of chloroform and approximately 2.5 µl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 µl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 µl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. using the strand pattern to detect a change in the body of the human donor.

9. **(Amended)** ~~The method of claim 6 in which the step of centrifuging the second blood cell mixture is performed for approximately fifteen (15) minutes at approximately 11,000 rpm~~.

A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of blood from a human donor with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately one (1) volume of Tris-buffer;

ii. adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any

disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which is not smooth throughout most of the strand's length.

10. **(Amended)** ~~The method of claim 6 in which the step of cooling the second liquid phase is performed by placing the second liquid phase on ice for approximately fifteen (15) minutes~~.

A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of blood from a human donor with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately one (1) volume of Tris-buffer;

ii. adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which has a plurality of beads and a substantial discontinuity with associated branching.

11. **(New)** A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of blood from a human donor with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately one (1) volume of Tris-buffer;

ii. adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which has a looped portion and a substantial discontinuity with associated branching.

12. **(New)** A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of the human blood with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately 5 μl of Tris-buffer;

ii. adding approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 μl of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately 10 μl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 μl of chloroform and approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 μl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 μl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which is not smooth throughout most of the strand's length.

13. **(New)** A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of the human blood with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately 5 μl of Tris-buffer;

ii. adding approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 μl of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately 10 μl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 μl of chloroform and approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 μl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 μl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which has a plurality of beads and a substantial discontinuity with associated branching.

14. **(New)** A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of the human blood with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately 5 μl of Tris-buffer;

ii. adding approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 μl of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately 10 μl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 μl of chloroform and

approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 μl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 μl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which has a looped portion and a substantial discontinuity with associated branching.

15. **(New)** The method of claim 7, 8, 9, 10, 11, 12, 13 or 14 in which the Tris-buffer consists of 0.5 M Tris, 0.2 M EDTA, 0.6% NaCl, having a pH of between 10.3 and 10.4.

16. **(New)** The method of claim 7, 8, 9, 10, 11, 12, 13 or 14 in which the step of centrifuging the first blood cell mixture is performed for approximately ten (10) minutes at 11,000 rpm.

17. **(New)** The method of claim 7, 8, 9, 10, 11, 12, 13 or 14 in which the step of centrifuging the second blood cell mixture is performed for approximately fifteen (15) minutes at 11,000 rpm.

18. **(New)** The method of claim 7, 8, 9, 10, 11, 12, 13 or 14 in which the step of cooling the second liquid phase is performed by placing the second liquid phase on ice for approximately fifteen (15) minutes.

19. **(New)** A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of blood from a human donor with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately one (1) volume of Tris-buffer;

ii. adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. using the strand pattern to detect a change in the body of the human donor.

20. **(New)** A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of the human blood with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

i. preparing approximately 5 μl of Tris-buffer;

ii. adding approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 μl of Tris-buffer to produce a buffer diluted phenol; and

iii. adding approximately 10 μl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 μl of chloroform and approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 μl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 μl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. using the strand pattern to detect a change in the body of the human donor.